EXPRESS MAIL LABEL NO.: EV980040306US DATE: December 5, 2007

TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US)**

ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-066

CONCERNING A SUBMISSIO	ON UNDER 35 U.S.C. 371	10.5. APPLICATION NO. (if known, see 37 CFR 1.5)					
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED					
PCT/US2005/017292 TITLE OF INVENTION	17 May 2005	17 May 2004					
HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS							
APPLICANT(S) FOR DO/EO/US Adrian Ashley, Paul Lamb, Donald Mac Donald, John Miller, Martin J. Oliver, and Mathew Pollard							
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:							
1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.							
2. x This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.							
This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.							
4. The US has been elected (Article 31).							
5. A copy of the International Applicati	ion as filed (35 U.S.C. 371 (c)(2))	,					
a. is attached hereto (required onl	y if not communicated by the Internatio	nal Bureau).					
b. has been communicated by the	International Bureau.						
c. is not required, as the application	on was filed in the United States Receiv	ring Office (RO/US).					
6. An English language translation of t	the International Application as filed (35	5 U.S.C. 371(c)(2)).					
a. is attached hereto.							
b. has been previously submitted in	under 35 U.S.C. 154(d)(4).	cle 19 (35 U.S.C. 371(c)(3)) ional Bureau).					
7. Amendments to the claims of the In	ternational Application under PCT Artic	cle 19 (35 U.S.C. 371(c)(3))					
a. are attached hereto (required or	nly if not communicated by the Internat	ional Bureau).					
b. have been communicated by the	e International Bureau.	nents has NOT expired. CT Article 19 (35 U.S.C. 371(c)(3)).					
c. have not been made; however,	the time limit for making such amendm	ents has NOT expired.					
d. have not been made and will no	t be made.	Dillo.					
8. An English language translation of t	the amendments to the claims under P	CT Article 19 (35 U.S.C. 371(c)(3)).					
9. x An oath or declaration of the invent	or(s) (35 U.S.C. 371(c)(4)). (6-Execute	d)					
10. An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).	the annexes of the International Prelim	inary Examination Report under PCT					
items 11 to 20 below concern docun	nent(s) or information included:						
11. An Information Disclosure Statem	nent under 37 CFR 1.97 and 1.98.						
12. An assignment document for record	ding. A separate cover sheet in compli	ance with 37 CFR 3.28 and 3.31 is included.					
13. A preliminary amendment.							
14. x An Application Data Sheet under 37 CFR 1.76. Supplemental							
15. A substitute specification.							
16. A power of attorney and/or change	e of address letter.						
17. A computer-readable form of the s	equence listing in accordance with Po	CT Rule 13 <i>ter.</i> 2 and 37 CFR 1.821 – 1.825.					
18. A second copy of the published In	ternational Application under 35 U.S.0	C. 154(d)(4).					
19. A second copy of the English lang	uage translation of the international a	pplication under 35 U.S.C. 154(d)(4).					

PTO-1390 (Rev. 09-2007)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. PCT/US2005/017292			ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-066					
20. X Other items or information: Copy of Notification Of Missing Requirements Under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), Petition For Extension Of Time (4 mo.), Return Receipt Postcard								
The foil	lowing fees have	e been submitte	ed				CALCULATION	S PTO USE ONLY
i —	-))			\$310	\$	S THO GOL GREE
If the written opin prepared by I	PEA/US indicates :	A/US or the internal claims satisfy p	ational preliminary exam ovisions of PCT Article 3	33(1)	-(4)	\$0	\$	
All other situations \$210 23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB. \$410					\$0 TO as an \$100 ce or	\$		
	TOTAL OF 21, 22					•	\$ 0.0	0
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$260 for each additional 50 sheets of paper or fraction thereof.				dium or				
Total Sheets	Extra Sheets		additional 50 or fraction up to a whole number)			RATE		
- 100 =	/50 =				x S	\$260.00	\$	
			e, examination fee, or the (37 CFR 1.492(h)).	oat	n or decl	laration	\$ 130.0	00
CLAIMS	-	MBER FILED	NUMBER EXTRA		R	ATE		
Total clair	<u>+</u>	- 20 =	0	×	x	\$50	0.0	
Independent	ENDENT CLAIM(S	- 3 =	0	×	* +	\$210	0.0	0
MOLTIPLE DEP	ENDENT CLAIM(S	(ii applicable)	TOTAL OF A	<u> </u>		\$370 CULATIONS =	\$ 130.0	10
Applican	t claims small entit	y status. See 37 C	FR 1.27. Fees above a				100.0	
						SUBTOTAL =	\$ 130.0	00
			anslation later than 30 m	nonth	s from t		\$	
claimed priority date (37 CFR 1.492(i)). TOTAL NATIONAL FEE =			TIONAL FEE =	\$ 130.00				
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$				
by an appropriate cover sheet (or or No.20, 6.61). 440.66 per property			\$					
TOTAL FEES ENCLOSED =			\$ 130.00					
			Amount to be refunded:	\$				
			- · · · · · · · · · · · · · · · · · · ·				Amount to be charged	\$

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a. A check in the amount of \$ to cover the abo	ve fees is enclosed.						
b. x Please charge my Deposit Account No. 12-1095 in the ame A duplicate copy of this sheet is enclosed.	ount of \$130.00 to cover the above fees.						
	The Commissioner is hereby additionated to charge any additional rees which that you required, or created by overpayment to be posterior						
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.							
ADVISORY: If filing by EFS-Web, do NOT attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is not recommended and by doing so your credit card Information may be displayed via PAIR . To protect your information, it is recommended paying fees online by using the electronic payment method.							
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not beer filed and granted to restore the International Application to pending state	met, a petition to revive (37 CFR 1.137(a) or (b)) must be us.						
SEND ALL CORRESPONDENCE TO:	SIGNATURE P. Foly						
	Shawn P. Foley						
CUSTOMER NUMBER: 000530	22.274						
	33,071 REGISTRATION NUMBER						





7	DANCMITTALLET	TED TO	THE UNITED STAT	EC	ATTORNEY'S DOCKET NUMBER
11			THE UNITED STAT	_	TEVNHC 3.3-066
CO			OFFICE (DO/EO/US)N UNDER 35 U.S.C.		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/594,861
	NATIONAL APPLICATION		INTERNATIONAL FILING D		PRIORITY DATE CLAIMED
	PCT/US2005/017292		17 May 2005		17 May 2004
	OF INVENTION STERILIZATION OF G	LUCOCOI	RTICOSTEROIDS		
APPLIC	CANT(S) FOR DO/EO/US				
<u>Adrian</u>	Ashley, Paul Lamb, Do	nald Mac	Donald, John Miller, Mart	in J. Oliv	er, and Mathew Pollard /US) the following items and other information:
Applica	3				
1	<u> </u>		s concerning a submission ur		
2. X	J				ubmission under 35 U.S.C. 371.
3.	This is an express reque include items (5), (6), (9)			ures (35 l	J.S.C. 371(f)). The submission must
4.	The US has been elected	d (Article 3	1).		
5.	A copy of the Internation	al Applicati	on as filed (35 U.S.C. 371 (c))(2))	
a.	is attached hereto (re	equired only	if not communicated by the	Internatio	nal Bureau).
b.	has been communicate	ated by the	International Bureau.		
C.	is not required, as the	e applicatio	n was filed in the United Stat	es Receiv	ring Office (RO/US).
6.	An English language trar	nslation of t	he International Application a	s filed (35	5 U.S.C. 371(c)(2)).
a.	is attached hereto.				
b.	has been previously	submitted u	nder 35 U.S.C. 154(d)(4).		
7.	<u> </u>		ernational Application under		
a.	are attached hereto (required on	ly if not communicated by the	e Internati	ional Bureau).
b.		•	International Bureau.		
c.	have not been made;	; however, t	he time limit for making such	amendm	ents has NOT expired.
d.	have not been made				
8.					CT Article 19 (35 U.S.C. 371(c)(3)).
9. x			r(s) (35 U.S.C. 371(c)(4)). (6		
0	An English language tran Article 36 (35 U.S.C. 371		ne annexes of the Internation	nal Prelimi	nary Examination Report under PCT
Item	ns 11 to 20 below conce	ern docum	ent(s) or information incl	uded:	
1.			ent under 37 CFR 1.97 and		
2.	An assignment documen	t for record	ing. A separate cover sheet	in complia	ance with 37 CFR 3.28 and 3.31 is included.
3.	A preliminary amendment	nt.			
4. x	An Application Data She	et under 3	7 CFR 1.76. Supplemental		
5	A substitute specification	1.			
6	A power of attorney and/	-			
7					CT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
8			emational Application under		
9	A second copy of the En	glish langu	age translation of the intern	ational ap	oplication under 35 U.S.C. 154(d)(4).

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/594,861 INTERNATIONAL APPLICATION NO. PCT/US2005/017292			ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-066					
20. x Other items or information: Copy of Notification Of Missing Requirements Under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), Petition For Extension Of Time (4 mo.), Return Receipt Postcard								
The following fees have been submitted						CALCULATION	S PTO USE ONLY	
	•))		•••••	\$310	\$	5 THO GOL GNET
22. Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					\$			
23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$0 as an . \$100 or . \$410	\$			
	TOTAL OF 21, 22						\$ 0.0	0
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$260 for each additional 50 sheets of paper or fraction thereof.					m or			
Total Sheets	Extra Sheets		of each additional 50 or fraction RATE (round up to a whole number)			TE		
- 100 =	- 100 = /50 = x \$260.00				0.00	\$		
			, examination fee, or the (37 CFR 1.492(h)).	e oath			\$ 130.0	0
CLAIMS	NUM	IBER FILED	NUMBER EXTRA	<u> </u>	RATE			
Total clair		- 20 =	0	×	<u> </u>	50	0.0	
Independent		- 3 =	0	×		210	0.0	
MULTIPLE DEP	ENDENT CLAIM(S	(ii applicable)	TOTAL OF A	ــــــــــــــــــــــــــــــــــــــ		ATIONS =	\$ 130.00	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.								
SUBTOTAL:			BTOTAL =	\$ 130.00				
Processing fee of claimed priority d	f \$130.00 for furnishate (37 CFR 1.492)	ning the English tra	anslation later than 30 m	nonths	from the e	earliest	\$	
TOTAL NATIONAL FEE			NAL FEE =	\$ 130.00				
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property			panied +	\$				
by all appropriate cover shock (or or incl.es, e.e.). Or elect per property						\$		
TOTAL FEES ENCLOSED =			\$ 130.00					
							Amount to be refunded:	\$
							Amount to be charged	\$

	An annually about forces					
a. A check in the amount of \$	to cover the above fees is enclo		ata ana an tha an tao an faoigi S			
b. X Riease charge my Depositi Account No. 12-10 Adduptier to copy of this sheet its enclosed.	095 in the amount of \$	130:00	to cover the above fees.			
The Commissioner is hereby authorized to charge a Account No. 12-1095 Addupticate	ny additional fees which may be n copy of this sheet is enclosed;	equired, or credit	any overpayment to Deposit			
d. Fees are to be charged to a credit card. WARNING not be included on this form. Provide credit card mailed or faxed to the USPTO. However, when paying	: Information on this form may be information and authorization on F	come public. Cree	TO-2038 should only be			
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NOTE: Where an appropriate time limit under 37 CFR 1. filed and granted to restore the international Application		n to revive (37 (CFR 1.137(a) or (b)) must be			
SEND ALL CORRESPONDENCE TO:	SIGNATI	gun P.	Foly_			
	NAME	Shawn P.	Foley			
CUSTOMER NUMBER: 000530		33,07				